

## **REMARKS**

Claims 80, 81, 83-92, 94-96, 104-106, and 109-117 are pending in the instant application. Claims 1, 83, 84, 91, 95, 96 and 112 have been amended to clarify what Applicant regards as the invention. Specifically, claim 1 has been amended to specify in the preamble the processes measured in the body of the claim and to specify that the HSP fragment is a receptor-binding fragment. Support for the amendment to claim 1 is found in the specification, *e.g.*, at page 38, line 32 to page 39 line 4, and at page 13, lines 27-28. Claims 83, 84, 91, 95, 96 and 112 have been amended for clarity. Claim 95 has also been amended to specify that in the alternative the receptor-binding fragment of the HSP is labeled. Support for the amendment to claim 95 is found in the specification, *e.g.*, at page 13, lines 27-28, and at page 29, lines 6-9. Claims 85-87 and 89-92 remain withdrawn as allegedly directed to a nonelected invention. Claims 85-87 and 89-92 are directed to specific embodiments of the test compound of claim 80, *i.e.*, wherein the test compound is an antibody or a peptide. Claim 80 is being examined in view of Applicant's election of a "small molecule" test compound, as discussed below in the Interview Summary. Applicant understands that if claim 80 is otherwise found allowable with respect to "small molecules" then the Examiner will examine the claims with respect to the other test compounds recited in claims 85-87 and 89-92. Accordingly, Applicant respectfully requests rejoinder of claims 85-87 and 89-92 at such time as claim 80 is deemed allowable with respect to a small molecule test compound.

### **1. INTERVIEW SUMMARIES**

#### **SUMMARY OF OCTOBER 6, 2005 INTERVIEW**

Applicant and Applicant's representatives thank Examiner Chrisopher Yaen and Examiner Sheila Huff for the courtesy of the telephonic interview of October 6, 2005 in connection with the above-identified application. Pursuant to 37 C.F.R. § 1.133 and M.P.E.P. 713.04, Applicant present this Interview Summary Record of the interview of October 6, 2005 between Examiners Yaen and Huff, and Applicant's representatives Adriane M. Antler and Muriel M. Liberto.

The issues raised in the Office Action dated May 18, 2005 and Applicant's response to that Office Action, mailed August 18, 2005, were discussed in the interview.

#### **Rejections Under 35 U.S.C. § 112**

The rejections under 35 U.S.C. § 112 were addressed first. At the outset,

Examiner Yaen stated that the rejection for lack of written description with respect to “small molecules” would be withdrawn.

The rejection under 35 U.S.C. § 112 for lack of enablement was then discussed. Agreement was not reached because Examiners Yaen and Huff maintained that the present assay method claims were “reach through claims” and therefore lacked enablement. Ms. Antler disagreed with the Examiners’ characterization of the present claims as “reach-through” claims because the present claims are not directed to the test compound identified by the claimed method, nor to the use of a product with modulating activity, but rather are directed to the assay method itself.

#### Restriction Requirement

The restriction to a “small molecule” test compound was subsequently discussed. In the May 18, 2005 Office Action, the Examiner objected to the term “test compound” in the claims as reading generically on compounds that are non-elected inventions and required that the claims be amended to recite a “small molecule” test compound. Ms. Antler stated Applicant’ position that the requirement to limit the claims to a “small molecule” test compound unfairly denied Applicant the ability to pursue claims of a scope wherein the test molecule is any molecule other than a small molecule, since the Examiner had not denoted any restriction group of that breadth.

#### SUMMARY OF NOVEMBER 7, 2005 INTERVIEW

Applicant and Applicant’s representatives thank Supervisory Patent Examiner (“SPE”) Larry Helms, Examiner Chrisopher Yaen and Examiner Sheila Huff for the courtesy of the telephonic interview of November 7, 2005 in connection with the above-identified application. Pursuant to 37 C.F.R. § 1.133 and M.P.E.P. 713.04, Applicant presents this Interview Summary Record of the interview of November 7, 2005 between SPE Helms, Examiner Yaen, Examiner Huff, and Applicant’s representatives Adriane M. Antler and Muriel M. Liberto, and representatives of the licensee, Antigenics, Inc., Lauren Foster and Gojeb Frehywot.

At the outset, Examiner Yaen informed Applicant’s attorney that he had issued a new non-final Office Action, mailed November 2, 2005, in which the basis for a rejection for lack of enablement had been changed, and the basis was no longer the Examiner’s assertion that the claims were impermissible “reach through” claims. However, Examiner Yaen explained that he issued a rejection for lack of enablement based on an alleged lack of a connection between the “HSP- $\alpha$ 2M receptor mediated process” of the preamble and the actual activities

measured in the body of claim 80, namely HSP binding activity, HSP uptake activity, or HSP-mediated antigen representation activity. Ms. Antler then asked if amending the claim to incorporate the actual activities measured into the preamble of claim 80 would overcome this rejection, and Examiner Yaen indicated that such an amendment would overcome the rejection. Examiner Yaen stated that there were no other rejections to the claims in the new Office Action.

Ms. Antler asked whether the Examiner was maintaining his objection to the term “test compound” in the claims as reading generically on compounds that are non-elected inventions. Ms. Antler reiterated her position that requiring a restriction of the invention to “small molecules,” rather than a species election of “small molecules,” amounted to a limitation of Applicant’s claim scope for reasons unrelated to patentability, without recourse to pursue the broader claim scope to which Applicant is entitled in a divisional application because none of the other restriction groups were directed generically to test compounds “other than small molecules.” Further, Ms. Antler stated that removing this restriction requirement would not entail undue search and examination on the Examiner’s part. SPE Helms stated that if claim 80 is otherwise found allowable with respect to “small molecules” then Examiner Yaen will examine the withdrawn claims with respect to other test compounds.

2. **THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF ENABLEMENT, SHOULD BE WITHDRAWN**

In the Office Action mailed November 2, 2005, the Examiner rejected claims 80, 81, 83, 84, 88, 94-96, 104-106, and 109-117 as allegedly lacking enablement because “[t]he specification has not provided any nexus between determining the levels of HSP activities [as recited in the body of claim 80] to means of ‘modulating an HSP- $\alpha$ 2M receptor mediated processs’ as claimed [in the preamble of claim 80]. The Examiner contends that, “[i]nstead what the specification has prophetically provided is guidance on methods of determining HSP activities, such as binding, uptake activity, and antigen representation” (internal quotations omitted)(see page 3 of the November 2, 2005 Office Action).

In response, Applicant has amended the claims to recite in the preamble that the process is HSP binding activity, HSP uptake activity, or HSP-mediated representation activity, thus obviating the rejection. During the November 7, 2005 interview discussed above, Examiner Yaen stated that incorporating the actual activities measured in the body of claim 80 into the preamble of claim 80, as now done, would overcome this rejection.

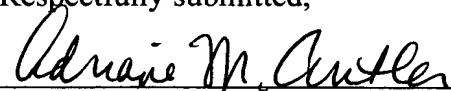
In summary, Applicant submits that amended claim 80 and its dependent claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and respectfully requests that the Examiner withdraw this rejection.

**CONCLUSION**

Entry of the foregoing amendment and remarks into the record of the above-identified application is respectfully requested. Applicant submits that the remarks and amendments made herein now place the claims in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Date: February 2, 2006

Respectfully submitted,

  
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